IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Lex P. Jansen et al.	Art Unit	: 3731
Serial No.	: 10/063,125	Examiner	: Sarah K. Webb
Filed	: March 22, 2002	Conf. No.	: 5949
Title	: MRI AND X-RAY COMPATIBLE STENT MATERIAL		

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Commissioner for Patents
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BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is Boston Scientific Scimed, Inc. (formerly SciMed Life Systems, Inc.)

(2) Related Appeals and Interferences

There are no related appeals or interferences.

(3) Status of Claims

Claims 2, 4, 5, 9-25, 29-31 are canceled

Claims 1, 3, 6-8, 26-28, and 32-38 stand rejected and are under appeal.

(4) Status of Amendments

There are no pending amendments.

(5) Summary of Claimed Subject Matter

This invention features stents incorporating alloys having specific percentage ranges of tungsten and rhenium. Claims 1 and 32 are independent in form. Each independent claim requires an expandable medical implant for implantation in a bodily vessel the implant having:

- a flow passage therethrough,
- being in the form of a stent comprising a body having a generally tubular shape,
- the body capable of maintaining patency in a blood vessel,
- the body consisting essentially of an alloy comprising tungsten and rhenium.

Claim 1 (as well as dependent claims 3, 6-8, and 26-28) specify that in the alloy comprising tungsten and rhenium, tungsten is present in an amount ranging from about 75 weight percent to about 99 weight percent. Claim 32 (and dependent claims 33-38) specify that in the alloy comprising tungsten and rhenium, rhenium is present in an amount ranging from about 1 weight percent to about 25 weight percent.

The presence of the tungsten-rhenium alloy having the required weight percentages in the claimed stent is important to enhance the stents radiopacity without interfering with MRI compatibility or impairing other important stent properties, such as the elasticity of the material.

Stents are medical implants involving complex structures having a variety of mechanical and material properties unique to the performance of stents during and after deployment. Stents are typically made from strands of material formed into a tube, of rolled sheets of material with openings, or of tubes with material removed therefrom to form a stent pattern. Stents formed of tubes with material removed perform differently than stents formed of strands by braiding, knitting, or the like. Stents are desirably expandable to open the body lumen at the point of deployment and to maintain the patency of the body vessel. Stents may be balloon expandable, self-expanding or a combination of self expanding and balloon expandable. Because stents are delivered through often-tortuous vessels, they must also be flexible. The stent structure may influence the flexibility and expandability of the stent. In order to achieve a desirable flexibility and expandability, the stent material should also have a high modulus of elasticity. At the same time the stent material should be sufficiently radiopaque to be visible under fluoroscopy. And with widespread use of Magnetic Resonance Imaging (MRI), it is desirable for the stent material

to be MRI compatible so as not to distort any magnetic resonance images that may be taken of the body in the region of the stent.

In short, there are a great many considerations involved in the claimed alloy composition. The claimed alloys with the specified weight percentages of tungsten and rhenium have extremely useful properties for stents, including a high modulus of elasticity for desired flexibility and expansion, as well as improved radiopacity and MRI compatibility. These points are presented in depth in the specification, for example, in paragraphs, 2-5 and 29-34 of the published application.

The tungsten-rhenium alloy having the specified weight percentages featured in the independent claims provides an important solution to the need for a flexible, expandable stent with suitable radiopacity and MRI compatibility not found in the prior art.

(6) Grounds of Rejection

Claims 1, 2, 6-8, 26-28, and 32-38 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,443,498 (Fontaine) in view of U.S. Patent No. 5,628,787 (Mayer), and in further view of U.S. Patent No. 5,226,909 (Evans), and further in view of "Rhenium and Molybdenum/Tungsten Based Alloys: An Overview of Database" by Boris Bryskin and Jan C. Carlen.

(7) Argument

Claims 1, 3, 6-8, 26-28, and 32-38, of which 1 and 32 are independent in form, have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,443,498 (Fontaine) in view of U.S. Patent No. 5,628,787 (Mayer), and in further view of U.S. Patent No. 5,226,909 (Evans), and further in view of "Rhenium and Molybdenum/Tungsten Based Alloys: An Overview of Database" by Boris Bryskin and Jan C. Carlen.

As noted, each of the above listed claims requires "An expandable medical implant for implantation in a bodily vessel, the implant having a flow passage therethrough, the implant being in the form of a stent comprising a body having a generally tubular shape, the body capable of maintaining patency in a blood vessel, the body consisting essentially of an alloy comprising tungsten and rhenium." Claim 1 additionally requires a stent including an alloy

comprising tungsten and rhenium, wherein tungsten is present in an amount ranging from about 75 weight percent to about 99 weight percent. Claim 32 recites a stent including an alloy comprising tungsten and rhenium, wherein rhenium is present in an amount ranging from about 1 weight percent to about 25 weight percent.

The Examiner is unable to find prior art disclosing a stent comprising an alloy of tungsten and rhenium in the required percentages. Moreover, none of the four references cited by the Examiner suggest or disclose that a stent comprising the claimed alloy with the required weight percentages would address the need for a flexible, expandable stent with a suitable radiopacity and MRI compatibility. Nor do the cited references disclose or suggest forming a stent of an alloy comprising tungsten and rhenium in the required weight percentages, as claimed. Indeed, with regard to the Examiner's cited references, and as discussed in detail below:

- The Examiner has acknowledged that Fontaine does not teach a stent with the claimed alloys;
- Mayer discloses a clad composite stent including a radiopaque core, but does not teach that tungsten-rhenium alloy in the required weight percentages is highly radiopaque and suitable for a flexible and expandable stent;
- Evans is not directed to stents but rather to atherectomy catheters having a cutting blade and does not disclose or suggest that the claimed tungsten-rhenium alloys would be suitable for flexible and expandable stents;
- Bryskin also teaches nothing about flexible and expandable stents.

The Examiner's rejection is improper because nothing in Fontaine in view of Mayer, in further view of Evans, and in further view of Bryskin would have suggested to those of ordinary skill in the art that they should make the claimed stent and that there would have been a reasonable expectation of success resulting in a flexible and expandable stent with the desired radiopacity and MRI compatibility.

A. The Federal Circuit requirements for a proper § 103 analysis

The Federal Circuit set forth the framework for a proper 35 U.S.C. § 103(a) analysis, stating that:

> A proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed [device]; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill in the art would have a reasonable expectation of success.

In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991). The Federal Circuit also has explained that a "reasonable expectation of success" cannot be based on hindsight knowledge that an inventor subsequently successfully makes the device. For example, in, the Court explained:

> That the inventors were ultimately successful is irrelevant to whether a person of ordinary skill in the art, at the time the invention was made, would have reasonably expected success.... The Court's finding to the contrary represents impermissible use of hindsight — using the inventors success as evidence that the success would have been expected.

Life Technologies, Inc. v. Clonetech Laboratories, Inc., 224 F.3d 1320, 1326 (Fed. Cir. 2000)

B. Fontaine fails to teach or suggest a stent formed of the claimed alloys.

The Examiner's rejection relies on Fontaine for disclosing a stent formed of a radiopaque material, such as tantalum. The Examiner has acknowledged that Fontaine does not disclose or suggest a stent formed of an alloy comprising tungsten and rhenium as claimed. "Fontaine discloses a stent structure formed of radiopaque metal, which can be tantalum.... Fontaine fails to form the stent from a tungsten-rhenium alloy." (Final Office Action, 9/21/06, p. 2.) In maintaining the final rejection of the claims, the Examiner relies on the secondary and tertiary references for the missing claim features. But none of the cited references discloses or suggests a stent formed of an alloy comprising tungsten and rhenium alloy in the required weight percentages and demonstrating the desired flexibility and expandability, as claimed.

C. Mayer does not teach that the claimed alloy is radiopaque or suitable for stents.

Mayer discloses a clad composite stent including, for example, a radiopaque core surrounded by a case. Mayer indicates that the radiopaque core can include metals (i.e., not alloys) such as gold, tungsten, iridium, rhenium, ruthenium, and depleted uranium (see, e.g.,

Mayer, col. 7, lines 7-9), or alloys such platinum-iridium and platinum-nickel (see, e.g., Mayer, col. 10, lines 60-64; and col. 11, lines 9-11). Mayer does not teach "that tungsten-rhenium alloy is highly radiopaque and suitable for medical devices", as asserted (but unsupported) by the Examiner. As indicated above, Mayer does not disclose or suggest a radiopaque alloy that includes tungsten and rhenium at all, let alone a stent having an alloy that includes tungsten and rhenium in the required weight percentages, as claimed. Thus, Mayer does not suggest to those of ordinary skill in the art (1) to make a stent including an alloy having tungsten and rhenium in the required weight percentages, and (2) that in so making a stent including an alloy having tungsten and rhenium, those of ordinary skill in the art would have a reasonable expectation of success resulting in a stent with the desired flexibility, expandability and MRI compatibility. See In re Vaeck. As a result, it is not clear how Mayer can address the deficiencies of Fontaine indicated above.

D. Evans is not directed to stents but rather to atherectomy catheters with blades

Evans has nothing to do with stents. Rather, Evans is directed to an atherectomy catheter 10 having a cutting blade 18 disposed with the interior of a cylindrical housing 14. (See Evans, col. 3, lines 40-44.) Evans discloses that the blade and/or the housing can be made radiopaque, and what materials are suitable for use:

> For all of the embodiments discussed above, it will be possible to coat or fill the housings and/or cutting blades with a radiopaque material of filler in order to facilitate viewing under a fluoroscope. Suitable radiopaque coating materials include palladium and gold, with bismuth, barium, and tantalum being suitable as fillers. Alternately, they may be constructed of radiopaque materials such as tungsten-rhenium or nitinol.

(Evans, col. 7, lines 36-42, emphasis added.) There is no indication whatsoever to those of ordinary skill in the art that they should make a stent to include an alloy having tungsten and rhenium, as claimed.

Furthermore, Evans does not provide a reasonable expectation that an alloy including tungsten and rhenium with the required weight percentages could be used successfully in a stent resulting in the desired mechanical and material properties. Evans, at best, is inviting further

research to be conducted to determine whether a tungsten-rhenium alloy would be suitable in a blade and/or a housing of an atherectomy catheter as a coating or as a filler. A stent, on the other hand, is a medical device typically used to support the wall of a body lumen and maintain patency. The stent is usually delivered in a small diameter condition through a tortuous body lumen to a treatment site and then expanded into contact with the vessel wall where it remains for extended periods. Thus, stents require a high degree of flexibility and expandability. Given this challenging application, an important factor in the performance of the stent is the material from which it is made. In particular, the choice of material includes consideration of a combination of mechanical properties, such as tensile strength and ductility, radiopacity, and metallurgical properties, such as resistance to stress cracking and corrosion. It is also desirable that the stent material not interfere with an MRI image. There is no teaching or suggestion whatsoever in Evans that any alloy including tungsten and rhenium could be used in a stent with a reasonable expectation of success. Thus, Evans does not meet either of the Vaeck criteria.

Moreover, insofar as the Examiner is asserting that because a tungsten-rhenium alloy is used in one specific medical device (the atherectomy catheter), then it would have been obvious to use the alloy in any other medical device (namely, a stent with its unique complex structure and desired mechanical and material properties), the Examiner is applying an improper obvious-to-try standard. See Jones v. Hardy, 727 F.2d 1524, 1530 (Fed. Cir. 1984) ("Obvious to try" is an improper consideration in a 35 U.S.C. § 103 analysis.) As discussed above, there is no teaching or suggestion whatsoever that an alloy including tungsten and rhenium could be used in a stent with a reasonable expectation of success.

E. Neither Bryskin or Rhenium Alloys teach the formation of a stent

The Examiner has indicated that it would be obvious to one of ordinary skill in the art to use a tungsten-rhenium alloy of the compositions taught by Bryskin in the stent of Fontaine, and the Examiner has pointed to the website for Rhenium Alloys, Inc. (www.rhenium.com/Materials/WRe/tungsten.html) ("Rhenium Alloys"), for its alleged suggestion that tungsten-rhenium alloys are excellent for medical applications. Neither of these references meet either of the Vaeck criteria.

Bryskin teaches nothing about stents. At best, Bryskin vaguely discloses that tungsten-rhenium compositions are known to have suitable mechanical properties for forming medical devices, but Bryskin does not indicate what the medical devices are. Rather, Bryskin states that tungsten-3 to 5 rhenium and up to 10 rhenium compositions have been found to be very attractive for fabrication of products such as x-ray targets and heat sinks (see, e.g., page 14, lines 15-17). These alloys can be used in x-ray targets apparently because of their ability to dissipate heat and low vapor pressure, as the x-ray target (specifically, the focal point of the anode in an x-ray tube) can get very hot where an electron beam strikes the target. But the fact that these alloys have good heat dissipation capabilities when used, for example, in x-ray targets, does not teach anything about their suitability for use in medical devices generally or in stents specifically. Thus, like Evans discussed above, there is no indication whatsoever in Bryskin to those of ordinary skill in the art that they should make a stent to include an alloy having tungsten and rhenium in the required weight percentages, as claimed. And there is no teaching or suggestion whatsoever in Bryskin that alloys including tungsten and rhenium could be used in a stent with a reasonable expectation of success resulting in the desired flexibility, expandability and MRI compatibility necessary in stents. In other words, like Evans, Bryskin does not meet either of the Vaeck criteria.

Applicants had previously argued that Bryskin does not provide sufficient evidence that its alloys are suitable for medical devices. In response to Applicants' arguments, the Examiner stated:

> Bryskin is not relied upon for this teaching. Bryskin is relied upon for providing examples of common W-Re compositions and mechanical properties of these compositions. In the abstract, Bryskin states that the W-Re alloys disclosed in the paper are common (line 8). In lines 14 and 15 on page 3, Bryskin states that the W-Re alloys are very attractive for x-ray targets.

(Final Office Action, 9/21/06, p. 4). The Examiner's response, however, is contrary with the Examiner's apparent motivation to combine Bryskin with Fontaine:

> It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use a tungsten-rhenium alloy of the compositions taught by Bryskin in the modified Fontaine stent, as Bryskin teaches that these common W-Re compositions are known to have suitable mechanical properties for forming medical devices.

(Final Office Action, 9/21/06, p. 3)

Bryskin, however, does not indicate what medical devices would be "suitable." The Examiner's characterization of Bryskin's alloys as having suitable mechanical properties for forming any medical devices lacks support and is overly broad. At best, Bryskin indicates that the alloys can be used in x-ray targets, but this indication does not teach anything about the suitability of the alloys for use in medical devices generally or in stents specifically as discussed above. Also, Applicants do not dispute the alloys may have been known, but the issue is whether there is any indication or suggestion in the reference that would have suggested to those of ordinary skill in the art to make a stent with the alloys as claimed, or that tungsten-rhenium alloys in the required weight percentages could be used in a stent with a reasonable expectation of success resulting in the desired mechanical and material properties. Here, Bryskin does not provide any such indication or suggestion, and the Examiner has not provided any reasoning of how alloys having properties suitable for an x-ray target would have motivated one skilled in the art to use the same alloys in a stent.

Rhenium Alloys also teaches nothing about stents. At best, Rhenium Alloys discloses that tungsten-rhenium alloys are excellent for medical applications, but Rhenium Alloys provides no examples of a "medical application." Instead, Rhenium Alloys focuses on the thermal properties of tungsten-rhenium alloys. But the fact that these alloys have good ductility after exposure to heat or can be exposed to extreme heat does not teach anything about their suitability for use in medical devices generally or in flexible and expandable stents. As used by Rhenium Alloys, a medical application, when read in context, could range anywhere from x-ray targets (for general medical diagnostic and angio- and cardiography to computer tomography) to isotopes for cancer radio-treatment. Thus, like the other cited references discussed above, there is no indication in Rhenium Alloys to those of ordinary skill in the art that they should make a stent to include an alloy having tungsten and rhenium with the required weight percentages, as claimed. There is also no teaching or suggestion in Rhenium Alloys that alloys including

tungsten and rhenium could be used in a stent with a reasonable expectation of success resulting in a stent having the desired flexibility, expandability, and MRI compatibility. Like the other cited references, Rhenium Alloys also does not meet either of the Vaeck criteria.

In response to Applicants' previous arguments, the Examiner stated:

> On the website for Rhenium Alloys, Inc. (provided in the Office Action dated 6/23/04), it is specifically stated in line 6 that tungsten-rhenium alloys are excellent for medical applications. There is sufficient motivation and evidence in the prior art to form a stent as set forth in the claims.

(Final Office Action, 9/21/06, p. 4.) Again, Rhenium Alloys indicates that the alloys can be used in "medical applications", but this indication does not teach anything about the suitability of the alloys for use in medical devices generally or in stents specifically, as discussed above. Also, Applicants do not dispute that tungsten-rhenium alloys may have been known, but the issue is whether there is any indication or suggestion in the reference that would have suggested to those of ordinary skill in the art that they should make a stent with tungsten-rhenium alloys having the required weight percentages, or that the alloys could be used in a stent with a reasonable expectation of success resulting in a stent with the desired mechanical and material properties. Here, Rhenium Alloys does not provide any such indication or suggestion. The Examiner has made a conclusory statement, without providing any reasoned analysis of how alloys having properties suitable for an x-ray target would have motivated one skilled in the art to use the same alloys in a flexible and expandable stent.

F. The cited references fail to teach the claimed subject matter and do not suggest to one skilled in the art to make a stent with the claimed alloys or that an alloy including tungsten and rhenium could be used in a stent with a reasonable expectation of success.

Applicants have provided a detailed analysis of why the 35 U.S.C. § 103(a) rejection is improper. The Examiner has acknowledged that Fontaine does not disclose or suggest a stent including the claimed alloy. As discussed above, none of the other cited references would have suggested to those of ordinary skill in the art that they should make a stent with the claimed

alloys, or that an alloy including tungsten and rhenium could be used in a stent with a reasonable expectation of success resulting in a stent with the desired properties.

The rejection, on the other hand, is cobbled together with the reasoning that because one radiopaque material—namely, tantalum—has been used in a stent, then any other radiopaque material—such as tungsten-rhenium—used in any other medical device could be applied to a stent. This is clearly an improper rejection based on an obvious-to-try standard. Indeed, none of the cited references teaches or suggests that an alloy including tungsten and rhenium in the required weight percentages used in a stent would have a reasonable expectation of success resulting in a stent having the desired flexibility, expandability and MRI compatibility.

G. Conclusion

In light of the discussion above, Applicants request that the rejections of claims 1-10, 19-24, and 33-38 be reversed, and that these claims be promptly allowed.

The brief fee in the amount of $500 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization.

Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: October 19, 2006

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Appendix of Claims

1. (Previously presented) An expandable medical implant for implantation in a bodily vessel, the implant having a flow passage therethrough, the implant being in the form of a stent comprising a body having a generally tubular shape, the body capable of maintaining patency in a blood vessel, the body consisting essentially of an alloy comprising tungsten and rhenium, wherein the tungsten is present in an amount ranging from about 75 weight percent to about 99 weight percent.

2. (Canceled)

3. (Previously presented) The medical implant of claim 1 wherein the alloy consists essentially of tungsten and rhenium.

4. (Canceled)

5. (Canceled)

6. (Previously presented) The medical implant of claim 1 wherein the rhenium is present in an amount ranging from about 25 weight percent to about 1 weight percent.

7. (Original) The medical implant of claim 1 wherein the modulus of elasticity is at least 400 GPa.

8. (Previously presented) The medical implant of claim 1 having a sidewall and a plurality of openings therein, the implant formed from a sheet or from a tube, the openings having been formed by removing material from the sheet or tube.

9-25. (Canceled)

26. (Previously presented) The medical implant of claim 1 further comprising a drug or a therapeutic agent on the body.

27. (Previously presented) The medical implant of claim 1 further comprising a coating on the body.

28. (Previously presented) The medical implant of claim 27 wherein the coating comprises a polymer.

29-31. (Canceled)

32. (Previously presented) An expandable medical implant for implantation in a bodily vessel, the implant having a flow passage therethrough, the implant being in the form of a stent comprising a body having a generally tubular shape, the body capable of maintaining patency in a blood vessel, the body consisting essentially of an alloy comprising tungsten and rhenium, wherein the rhenium is present in an amount ranging from about 1 weight percent to about 25 weight percent.

33. (Previously presented) The medical implant of claim 32, wherein the alloy consists essentially of tungsten and rhenium.

34. (Previously presented) The medical implant of claim 32, wherein the modulus of elasticity is at least 400 GPa.

35. (Previously presented) The medical implant of claim 32, having a sidewall and a plurality of openings therein, the implant formed from a sheet or from a tube, the openings having been formed by removing material from the sheet or tube.

36. (Previously presented) The medical implant of claim 32, further comprising a drug or a therapeutic agent on the body.

37. (Previously presented) The medical implant of claim 32, further comprising a coating on the body.

38. (Previously presented) The medical implant of claim 37, wherein the coating comprises a polymer.

Evidence Appendix

None

Related Proceedings Appendix

None